K071000



# 5. 510(K) SUMMARY

[As Required by 21 CFR 807.92]
Summary of Safety and Effectiveness

MAY 14 2007

| | |
|---|---|
| **Preparation date** | April 6th, 2007 |
| **Submitter** | |
| Name | INTRASENSE |
| Registration number | TBD |
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| **Contact Person** | Mr Stéphane CHEMOUNY<br>Phone number : (+33) 467 130 130<br>Fax number : (+33) 467 130 132 |
| **Device name** | |
| Common Name | System, Image Processing |
| Trade Name | MYRIAN |
| Model number | N/A |
| **Device classification** | |
| Classification name | System, Image Processing, Radiological |
| Code product | LLZ |
| Panel | 892 |
| Regulation number | 892.=2050 |
| Regulatory class | II |
| **Predicate devices** | [K052995] Cleared [November 8, 2005] [General Electric Medical Systems] [Advantage Workstation Version 4.3], manufactured by [General Electric Medical Systems]<br>[K061624] Cleared [June 27, 2006] [Vital Images, Inc.] [Vitrea2 Version 3.9], manufactured by [Vital Images, Inc.] |
| **Description** | Myrian® system is a software suite providing the following services :<br>Import of DICOM images from any DICOM modality, workstation or PACS<br>Visualization of DICOM images in thin MPR, thick MPR and full 3D volume rendering<br>Creation of VOI (Volume Of Interest) with dedicated tools<br>Calculation of volumes, surface and of average, minimum and maximum densities on VOI<br>Follow-up of patient examination<br>Generation of medical reports<br>Export of DICOM images to any format, DICOM entity or media |
| Explanation of how the device operates | Myrian® with its modules is designed to run on standard PC hardware. The hardware is all "off-the-shelf" standard computer components and may be purchased independently by the end user. |

**Intended use**

Myrian® with its modules is a software application that is used for reviewing medical images. Myrian® with its modules is designed to run on standard PC hardware. The hardware is all "off-the-shelf' standard computer components and may be purchased independently by the end user. Myrian with its modules receives digital images and data from various sources (including but not limited to CT, MR, US, RF modalities, computed and direct radiographic devices, secondary capture devices, scanners, imaging gateways or imaging sources like PACS).
Myrian® and its Modules can be used to communicate, to process, print and display medical images. Users have access to various image processing, Volume of Interest editing and measurement tools to assist them in viewing and quantifying images.
Myrian® and its Modules can be integrated with an institution's existing HIS or RIS for a fully integrated electronic patient record.

Typical users of Myrian® with its Modules are trained medical professionals, including but not limited to radiologists, technologists and clinicians.

When interpreted by a trained physician, filmed or displayed images on the Myrian® and its Modules may be used as a basis for diagnosis, except in the case of mammography images.
Myrian® with its Modules does not support the display of mammography images for diagnosis.

**Performance data**

Performance data were verified versus the requirements of the FDA "Guidance of the Content of Pre Market Submissions for Software Contained in Medical Devices"

User Site Testing, Benchmarking and clinical data analysis demonstrate that MYRIAN meet the required specifications. No adverse affects have been detected.

**Substantial equivalence summary**

The technological characteristics, features, specifications, materials, mode of operation, and intended use of MYRIAN device are equivalent to those of the predicate devices quoted above.

MYRIAN is the same as the predicate devices in K061624 and K052995

The differences that exist between the devices do not raise new issues of safety or effectiveness regarding MYRIAN Device.

It is substantially equivalent in terms of safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

INTRASENSE
% Mr. Nicolas Clary
Project Leader
CEISO
"Les Portes d'Espagne" – Bât. B – 99, route d'Espagne 31100
Toulouse 31100
FRANCE

MAY 14 2007

Re: K071000
Trade/Device Name: Myrian
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 6, 2007
Received: April 13, 2007

Dear Mr. Clary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## 4. INDICATIONS FOR USE

510(k) Number (if known): K071000

Device Name: Myrian

Indications for Use:

Myrian is a multi modality medical diagnostic device. It is aimed at reviewing and analysing anatomy and pathology. It also includes DICOM communication capabilities and media interchange features (printing, CD burning, storing). It runs on any standard PC including laptops that might be purchased independently by the end user. It provides user a set of tools meant to create and modify volumes of interest.

This device is not indicated for mammography use. Lossy compressed mammography images and digitized film screen images must not be used for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 mega pixel resolution and meets other technical specifications approved by the FDA.

Prescription Use (Part 21 CFR 801 Subpart D) 1.1 AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

**(Division Sign-Off)**
**Division of Reproductive, Abdominal, and Radiological Devices**
**510(k) Number** K071000